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Filed : December 5, 2002

REMARKS

Claims 1-12 are currently pending. Claims 1 and 12 have been amended for clarification purposes as noted below.

Claim 1 has been amended to recite a closed loop heating system for a nipple aspirate fluid aspiration device, comprising a plurality of inflatable bladders for providing compression of a breast; a reservoir; and a fluid flow path for placing the bladders in fluid communication with the reservoir; wherein said fluid flow path comprises a movable wall such that a fluid in the system can be moved by application of external pressure to the movable wall.

Claim 12 has been amended to recite an array of inflatable bladders for use in a breast pump, comprising at least a first and a second inflatable bladder; a mechanical link between the first and second bladder; a flow path extending between the first and second bladder; a reservoir; and a flow path between the reservoir and the first and second bladder; said flow path comprising a movable wall such that a fluid in the system can be moved by application of external pressure to the movable wall. Applicants note that basis in the original disclosure for amendments to both Claims 1 and 12 can be found, for example, at paragraph [0112] of the specification, and is thus proper under 35 U.S.C. § 112, paragraph 1.

The Examiner rejected claims 1, 4, and 5 on the basis of an obvious-type double-patenting rejection over claims 1 and 6-8 of U.S. Patent No. 6,875,184. The Examiner also rejected claims 1, 4-6, 11, and 12 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 3,995,621 to Fletcher et al ("Fletcher"). Furthermore, the Examiner rejected claims 1-4, 6, 11 and 12 as being anticipated by U.S. Patent No. 5,507,792 to Mason et al ("Mason"). Moreover, the Examiner rejected claims 7-10 as being unpatentable over Fletcher, and also as unpatentable over Mason.

Obviousness-type Double-Patenting Rejection

The Examiner rejected claims 1, 4, and 5 on the basis of an obvious-type double-patenting rejection over claims 1 and 6-8 of U.S. Patent No. 6,875,184. Please find attached a Terminal Disclaimer over claims 1 and 6-8 of U.S. Patent No. 6,875,184 as proper under 37 C.F.R. § 1.321(a); we thus request the Examiner withdraw this rejection.

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Rejections under 35 U.S.C. § 102(b)

Claims 1-6, 11

Claims 1, 4-6, and 11 have been rejected as anticipated by Fletcher; Claims 1-4, 6, and 11 have been rejected as anticipated by Mason. Applicants have amended claim 1 for clarification to recite a closed loop heating system for a nipple aspirate fluid aspiration device, comprising a plurality of inflatable bladders for providing compression of a breast; a reservoir; and a fluid flow path for placing the bladders in fluid communication with the reservoir; wherein said fluid flow path comprises a movable wall such that a fluid in the system can be moved by application of external pressure to the movable wall. Applicants respectfully traverse this rejection because neither Fletcher nor Mason identically teaches every element of amended claim 1. See M.P.E.P. § 2131 (stating that in order to anticipate a claim, a prior art reference must identically teach every element of the claim).

Fletcher discloses cooling panels with a multiplicity of individual sections 20 connected to cooling liquid inlet line 24 and to cooling liquid outlet line 25 through a connecting Y coupler 26. Each panel has an inlet tube 32 and outlet tube 33 connected to the outlet cooling line 25 and the inlet cooling line 24, respectively (see col. 3, ll. 40-46, Fig. 2). The cooling fluid from pumping means 40, which is preferably a water pump, flows under pressure to a solenoid valve 41, and there the flow is routed either to bypass line 43 or through refrigeration unit 42. Heating means 44 receives the cooling fluid from either bypass line 43 or refrigeration unit 42. Cooling fluid then flows to reservoir 47 then into inlet line of the brassiere 24 (see col. 4, ll. 27-40, Fig. 4).

Mason discloses a therapeutic treatment device 10 with a fluid-retaining heat transfer element 12, a fluid reservoir 14, and a unitary tubular sheath 16 enclosing a pair of fluid lines 18, 20 extending between the pad 12 and the fluid reservoir 14. The device further comprises a pump 22 which may be an elastomeric bulb 22 positioned in-line across the inlet line 18 relatively distal to both the pad 12 and the fluid reservoir 14, or an in-line electrically powered, motor-driven pump 102 in another embodiment (col. 10, ll. 53-59, Figs 1, 5).

Applicants contend that neither Fletcher nor Mason disclose, inter alia, a fluid flow path for placing the bladders in fluid communication with the reservoir; wherein said fluid flow path comprises a movable wall such that a fluid in the system can be moved by application of external

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pressure to the movable wall as defined in the specification of the present application. The fluid flow path is described as formed by inflation conduits 162, 172, inflatable bladders 152, and a fluid reservoir 260 (see paragraph [0136]). A pump 262, which may be a three or four-roller peristaltic pump, is in compressive contact with at least a portion of the exterior surface of one of the inflation conduits 162, and imparts a peristaltic pumping action thereto to force inflation media to flow through the inflation conduit 162. (see paragraph [0133]).

Applicants also note the specification discloses special advantages of the closed circuit fluid flow path as claimed. This closed loop structure may be easily removed from the associated pump and related electronics and replaced by a fresh closed loop part. The user does not need to come in contact with the heat exchange and inflation liquid. Nor does any part of the pump or associated device. This keeps the inflation media separate from any moisture-sensitive electronics (paragraph [0136]). Also, such a closed loop path conveniently also allows compression cycles such as from peristaltic rollers to be directly applied to the outside wall of the closed loop heating system, so that the pump never comes into direct contact with heat exchange fluid either during normal operation or during replacement of the closed loop. Furthermore, such a path may also allow compression cycles to be nonperistaltic cycles that are pulsatile within each cycle, such as the use of a platen or roller pump to provide pulsatile inflation of the inflatable bladders.

Neither the inlet 24 or outlet 25 cooling lines of Fletcher or fluid lines 18, 20 of Mason teach or even suggest a removable, closed loop fluid flow path comprising a movable wall such that fluid in the system can be moved by application of external pressure to the movable wall (such as by a peristaltic roller pump). Both Fletcher and Mason merely disclose, in this regard, movement of fluid as a result of an in-line pump, where fluid must come into direct contact with the pump.

Therefore, it is not possible to exchange a single closed loop component in the devices of Fletcher or Mason while preventing direct contact between the heat or pressure exchange fluid and all other parts of the system both during operation and during replacement of the closed loop. Because the distinct characteristics defining the closed fluid flow loop as claimed are absent in the cited prior art references, claim 1 is not anticipated by any of the aforementioned references. We thus request that the Examiner withdraw this rejection. Applicants note that claims 2-6 and

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11 depend from claim 1 and contain all of the limitations thereof in addition to further distinguishing features; thus Applicants submit that these claims are in condition for allowance as well.

Claim 12

Claim 12 has been rejected as anticipated by Fletcher, and also as anticipated by Mason. Applicants respectfully traverse this rejection because neither Fletcher nor Mason identically teaches every element of the claim. Claim 12 recites an array of inflatable bladders for use in a breast pump, comprising at least a first and a second inflatable bladder; a mechanical link between the first and second bladder; a flow path extending between the first and second bladder; a reservoir; and a flow path between the reservoir and the first and second bladder; said flow path comprising a movable wall such that a fluid in the system can be moved by application of external pressure to the movable wall. Applicants reiterate here the discussion of claims 1-6 and 11 above, and contend that neither reference cited by the Examiner teach or even suggest, inter alia, a removable, closed loop system, in which a flow path comprising a movable wall such that a fluid in the system can be moved by application of external pressure to the movable wall. Therefore, because the distinct characteristics defining the fluid flow path are absent in the cited prior art references, Claim 12 is not anticipated by any of the aforementioned references. We thus request that the Examiner withdraw this rejection.

Rejections under 35 U.S.C. § 103(a)

The Examiner rejected Claims 7-10 as being unpatentable over Fletcher, or alternatively as unpatentable over Mason. Applicants contend the obviousness rejection is improper because neither reference teaches or suggests all of the recited claim limitations, and furthermore, that a skilled artisan would have no motivation to produce the claimed features of the present application from either reference cited. See M.P.E.P. § 2143.

As noted above, claim 1, which claims 7-10 depend from, recites, inter alia, a fluid flow path for placing the bladders in fluid communication with the reservoir; wherein said fluid flow path comprises a movable wall such that a fluid in the system can be moved by application of external pressure to the movable wall. Applicants reiterate here the discussion of claims 1-6 and

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11 above, and contend that neither Fletcher nor Mason teach or even suggest, inter alia, a flow path comprising a movable wall such that a fluid in the system can be moved by application of external pressure to the movable wall. As claims 7-10 depend from claim 1 and contain all of the limitations thereof in addition to further distinguishing features, Applicants submit that this rejection should be withdrawn as well.

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CONCLUSION

For the reasons presented above, Applicants submit that the present application is in condition for allowance and respectfully request same. If any issues remain, the Examiner is cordially invited to contact Applicants' representative at the number provided below in order to resolve such issues promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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